

In response to the above rejections and in connection with the filing of a Request for Continued Examination (RCE) pursuant to 37 C.F.R. §1.114, Applicants have amended the claims which, when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

In the first instance, Applicants respectfully submit that the Sequence Listing has been amended to correct certain typographical errors. More specifically, Applicants have corrected two typographical errors in the nucleotide sequence of SEQ ID NO: 6 (human bcl-w) at nucleotide position 301, 404 and 405, as indicated in the attached marked-up copy of the amended Sequence Listing. Furthermore, the protein sequence in SEQ ID NO: 7 has been amended to correct two clerical errors appearing at positions 101 and 135. In addition, Applicants have corrected certain typographical errors in the nucleotide sequence of SEQ ID NO: 8 (murine bcl-w), as indicated in the attached marked-up copy of the amended Sequence Listing. The protein sequence in SEQ ID NO: 9 has been amended to correct certain clerical errors, as indicated in the attached marked-up copy of the amended sequence listing.

Applicants respectfully submit that the foregoing amendment does not introduce new matter. More specifically, the protein sequence of SEQ ID NO: 7 (human bcl-w) as amended is set forth in Figure 8 as originally filed. The protein sequence of SEQ ID NO: 9 (murine bcl-w) as amended is set forth in Figure 1 as originally filed. In addition, these protein sequences find support in Figures 9A and 9B of the priority document, Australian Provisional Application PN8965, filed on March 27, 1996. A courtesy copy of such priority document is enclosed for the Examiner's convenience (**Exhibit A**). The nucleotide sequences of SEQ ID NO: 6 and SEQ ID

NO: 8 as amended are also disclosed in Figure 9A and 9B, respectively, of the priority document.

Applicants further respectfully submit that the originally filed Figures 9A to 9B(iv), which set forth the nucleotide and protein sequences of human bcl-w and murine bcl-w, contain the same typographical errors as the original Sequence Listing. Accordingly, Applicants submit herewith substitute sheets of Figures 9A and 9B to replace the drawing sheets of Figures 9A to 9B(iv) originally filed. The substitute drawing of Figure 9B discloses the nucleotide sequence (SEQ ID NO: 6) and the encoded protein sequence (SEQ ID NO: 7) of human bcl-w. The substitute drawing of Figure 9B discloses the nucleotide sequence (SEQ ID NO: 8) and the encoded protein sequence (SEQ ID NO: 9) of murine bcl-w. These substitute sheets of drawings do not introduce new matter and are fully supported by the application as filed and by the priority document.

Turning to the claims, the Examiner rejects claims 1-4 under 35 U.S.C. §112, first paragraph as allegedly not enabled. The Examiner admits that the specification is enabling for an isolated nucleic acid molecule comprising SEQ ID NO: 6 or 8 which encodes the amino acid sequence of SEQ ID NO: 7 or 9. However, the Examiner contends that the specification does not provide enablement for all nucleic acid molecules encompassed by the claims. The Examiner states that the specification does not disclose any derivative of SEQ ID NO: 6 or 8, or a nucleic acid molecule encoding an amino acid sequence having at least 47% similarity to SEQ ID NO: 7 or 9, or a nucleic acid molecule which hybridizes under low stringency conditions to SEQ ID NO: 6 or 8 and which elicits a Bcl-w-related activity. It is the Examiner's opinion that it would take undue experimentation for those skilled in the art to practice the claimed invention.

Applicants respectfully disagree with the Examiner. Applicants respectfully submit that the present specification adequately teaches the molecules as claimed, including derivative and homologous sequences of SEQ ID NO: 6 or 8 that enhance cell survival. For example, the specification teaches the human bcl-w gene (SEQ ID NO: 6) and the murine bcl-w gene (SEQ ID NO: 8). The specification further teaches that the human Bcl-w protein and the murine Bcl-w share about 90% similarity. Moreover, the specification provides specific exemplification demonstrating that expression of the bcl-w gene enhances cell survival. See pages 35-36 of the specification. In light of the present teaching, those skilled in the art can isolate a nucleic acid molecule that either hybridizes to SEQ ID NO: 6 or 8, or encodes a protein that shares at least about 47% similarity to SEQ ID NO: 7 or 9, and determine whether the isolated molecule enhances cell survival. It is respectfully submitted that the experimentation required for those skilled in the art to make and use the claimed molecule is not undue.

However, in an effort to favorably advance the prosecution of the present case, Applicants have canceled claims 1-4 without prejudice, rendering the rejection thereof moot. Applicants reserve the right to pursue the subject matter of these canceled claims in a continuing application.

Applicants have also added claims 21-24, directed to nucleic acid molecules comprising SEQ ID NO: 6 or SEQ ID NO: 8, or encoding a protein having a sequence as set forth in SEQ ID NO: 7 or SEQ ID NO: 9. As the Examiner has acknowledged in the Final Action, the specification is enabling for these nucleic acid molecules.

Accordingly, withdrawal of the rejection of claims 1-4 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1 and 4 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 5,789,201 ("the '201 patent"). According to the Examiner, the '201 patent teaches nucleotide sequences encoding a bcl-2 homolog (bcl-y). The Examiner contends that the sequence search report provided by the Examiner shows that the human bcl-y gene of the '201 patent matches 97.4% to SEQ ID NO: 6 (human bcl-w) of the claimed invention, and 85% to SEQ ID NO: 8 (murine bcl-w) of the present invention; and that the human Bcl-y protein of the '201 patent matches 98.7% to SEQ ID NO: 7 (human Bcl-w).

It is respectfully submitted that the cancellation of claims 1-4 renders the rejection moot. Withdrawal of the rejection is therefore respectfully requested.

Applicants further submit that the nucleic acid molecules of claims 21-24 are not taught by the '201 patent. Applicants have provided herewith **Exhibit B**, illustrating the differences between the bcl-w sequences of the present application and the bcl-y sequences of the '201 patent. At page 1 of Exhibit B, the human bcl-w (SEQ ID NO: 7), the murine bcl-w (SEQ ID NO: 9), the human bcl-y of the '201 patent (SEQ ID NO: 4 of the '201 patent) and the rat bcl-y of the '201 patent are compared with one another. It is observed that the human bcl-w protein of the present application differs from the human bcl-y of the '201 patent at amino acid position 15, with Ala in human bcl-w and Glu in human bcl-y. The human bcl-w protein differs from the rat bcl-y of the '201 patent at amino acid position 7 ("A" in human bcl-w and "T" in rat bcl-y), position 124 ("E" in human bcl-w and "D" in rat bcl-y), and position 128 ("A" in human bcl-w and "T" in rat bcl-y). It is further observed that the murine bcl-w protein of the present application differs from the human bcl-y of the '201 patent at amino acid position 7 ("T" in murine bcl-w and "A" in human bcl-y), position 15 ("A" in murine bcl-w and "E" in human bcl-y), and position 124 ("D" in murine bcl-w and "E" in human bcl-y). The murine bcl-w protein of

the present application also differs from the rat bcl-y of the '201 patent at amino acid position 128 ("A" in murine bcl-w and "T" in rat bcl-y). Accordingly, protein sequences of SEQ ID NO: 7 and SEQ ID NO: 9 of the present application are not taught by the '201 patent, nor are the nucleic acid molecules encoding the protein of SEQ ID NO: 7 or SEQ ID NO: 9 (i.e., the subject matter of claims 21-22) taught by the '201 patent.

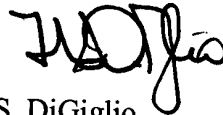
At page 2 of Exhibit B, the nucleotide sequence of the human bcl-w gene (SEQ ID NO: 6 of the present application) is compared with the human bcl-y and rat bcl-y genes of the '201 patent. Those nucleotides in the bcl-y genes which differ from the human bcl-w gene are indicated underneath the human bcl-w sequence. Clearly, the human bcl-w gene (SEQ ID NO: 6) of the present application is distinct from the human bcl-y and rat bcl-y genes of the '201 patent. Therefore, claim 23, drawn to a nucleic acid molecule comprising SEQ ID NO: 6, is not taught by the '201 patent.

Page 3 of Exhibit B illustrates the differences between the murine bcl-w gene (SEQ ID NO: 8) of the present application and the bcl-y genes of the '201 patent. Clearly, the murine bcl-w gene (SEQ ID NO: 8) of the present application is distinct from the human bcl-y and rat bcl-y genes of the '201 patent. Therefore, claim 24, drawn to a nucleic acid molecule comprising SEQ ID NO: 8 is not taught by the '201 patent.

Attached hereto is a marked-up copy of the amendment to the claims and to the Sequence Listing, entitled "Version with markings to show changes made"; a substitute paper and computer-readable copy of the Sequence Listing; a statement under §1.821(f) verifying that the content of the substitute paper copy and the substitute computer-readable copy of the Sequence Listing are the same; substitute sheets for Figures 9A and Figures 9B; Exhibit A and Exhibit B.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

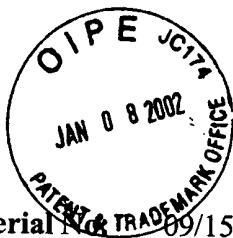
Respectfully submitted,



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Enclosures: Marked up version of the amendment to the claims and the Sequence Listing  
Substitute paper and computer-readable copy of the Sequence Listing  
Statement under §1.821(f)  
Substitute sheets of Figures 9A and 9B  
Exhibit A: Priority Document (Australian Provisional Application PN8965)  
Exhibit B: Comparison of bcl-w and bcl-y sequences



Serial No. 09/155,327

Date: November 9, 2001



**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the claims:**

Claims 1-4 have been canceled without prejudice.

Claims 21-24 have been added:

21. An isolated nucleic acid molecule, wherein said nucleic acid molecule encodes a protein comprising an amino acid sequence as set forth in SEQ ID NO: 7.

22. An isolated nucleic acid molecule, wherein said nucleic acid molecule encodes the amino acid sequence as set forth in SEQ ID NO: 9.

23. An isolated nucleic acid molecule wherein said nucleic acid molecule comprises the nucleotide sequence as set forth in SEQ ID NO: 6.

24. An isolated nucleic acid molecule wherein said nucleic acid molecule comprises the nucleotide sequence as set forth in SEQ ID NO: 8.

**In the Sequence Listing:**

The sequences in SEQ ID NO: 6-9 have been amended as follows:

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 <211> 583  
 <212> DNA  
 <213> HUMAN



<220>  
 <221> CDS  
 <222> (1)..(579)

<400> 6

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ttt gta ggt tat aag ctg agg cag aag ggt tat gtc tgt gga gct ggc	96
Phe Val Gly Tyr Lys Leu Arg Gln Lys Gly Tyr Val Cys Gly Ala Gly	
20 25 30	
ccc ggg gag ggc cca gca gct gac ccg ctg cac caa gcc atg cgg gca	144
Pro Gly Glu Gly Pro Ala Ala Asp Pro Leu His Gln Ala Met Arg Ala	
35 40 45	
gct gga gat gag ttc gag acc cgc ttc cgg cgc acc ttc tct gat ctg	192
Ala Gly Asp Glu Phe Glu Thr Arg Phe Arg Arg Thr Phe Ser Asp Leu	
50 55 60	
gcg gct cag ctg cat gtg acc cca ggc tca gcc cag caa cgc ttc acc	240
Ala Ala Gln Leu His Val Thr Pro Gly Ser Ala Gln Gln Arg Phe Thr	
65 70 75 80	
cag gtc tcc gac gaa ctt ttt caa ggg ggc ccc aac tgg ggc cgc ctt	288
Gln Val Ser Asp Glu Leu Phe Gln Gly Gly Pro Asn Trp Gly Arg Leu	
85 90 95	
gta gcc ttc ttt <sup>g</sup> ctc ttt ggg gct gca ctg tgt gct gag agt gtc aac	336
Val Ala Phe Phe <del>Leu</del> <sup>Val</sup> Phe Gly Ala Ala Leu Cys Ala Glu Ser Val Asn	
100 105 110	
aag gag atg gaa cca ctg gtg gga caa gtg cag gag tgg atg gtg gcc	384
Lys Glu Met Glu Pro Leu Val Gly Gln Val Gln Glu Trp Met Val Ala	
115 120 125	



ct  
 tac ctg gag acg cgg ctg g~~gc~~ gac tgg atc cac agc agt ggg ggc tgg 432  
 Tyr Leu Glu Thr Arg Leu Val Asp Trp Ile His Ser Ser Gly Gly Trp  
 130 135 140

gcg gag ttc aca gct cta tac ggg gac ggg gcc ctg gag gag gcg cgg 480  
 Ala Glu Phe Thr Ala Leu Tyr Gly Asp Gly Ala Leu Glu Glu Ala Arg  
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cgt ctg cgg gag ggg aac tgg gca tca gtg agg aca gtg ctg acg ggg 528  
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 165 170 175

gcc gtg gca ctg ggg gcc ctg gta act gta ggg gcc ttt ttt gct agc 576  
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 180 185 190

aag tgaa 583  
 Lys

<210> 7  
 <211> 193  
 <212> PRT  
 <213> HUMAN

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Pro Gly Glu Gly Pro Ala Ala Asp Pro Leu His Gln Ala Met Arg Ala  
 35 40 45

Ala Gly Asp Glu Phe Glu Thr Arg Phe Arg Arg Thr Phe Ser Asp Leu  
 50 55 60

Ala Ala Gln Leu His Val Thr Pro Gly Ser Ala Gln Gln Arg Phe Thr  
 65 70 75 80

Gln Val Ser Asp Glu Leu Phe Gln Gly Gly Pro Asn Trp Gly Arg Leu

85

90

95

Val Ala Phe Phe <sup>Val</sup>~~Leu~~ Phe Gly Ala Ala Leu Cys Ala Glu Ser Val Asn

100

105

110

Lys Glu Met Glu Pro Leu Val Gly Gln Val Gln Glu Trp Met Val Ala

115

120

125

Tyr Leu Glu Thr Arg Leu <sup>Ala</sup>~~Val~~ Asp Trp Ile His Ser Ser Gly Gly Trp

130

135

140

Ala Glu Phe Thr Ala Leu Tyr Gly Asp Gly Ala Leu Glu Glu Ala Arg

145

150

155

160

Arg Leu Arg Glu Gly Asn Trp Ala Ser Val Arg Thr Val Leu Thr Gly

165

170

175

Ala Val Ala Leu Gly Ala Leu Val Thr Val Gly Ala Phe Phe Ala Ser

180

185

190

Lys

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1

<sup>Ala</sup>

5

10

15

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85 90 95

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130 135 140

gcg ga<sup>g</sup> ttc aca gct cta tac ggg gac ggg gcc ctg gag ga<sup>g</sup> gca cgg 480  
Ala ~~Asp~~<sup>Glu</sup> Phe Thr Ala Leu Tyr Gly Asp Gly Ala Leu Glu ~~Asp~~<sup>Glu</sup> Ala Arg  
145 150 155 160

cgt ctg cgg gag gg<sup>g</sup> aac tgg gca tga<sup>c</sup> gtg ag<sup>g</sup> aca gtg<sup>c</sup> atg<sup>c</sup> acg ggg 528  
Arg Leu Arg Glu Gly Asn Trp Ala ~~Val~~<sup>Ser</sup> ~~Ser~~<sup>Val</sup> ~~Thr~~<sup>Arg</sup> ~~Val~~<sup>Thr</sup> ~~Val~~<sup>Leu</sup> Thr Gly Ala  
165 170 175

(to next page)

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 aag tga 581 582  
 (from previous page)

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 <213> Mouse

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 35 40 45  
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 50 55 60  
 Ala Ala Gln Leu His Val Thr Pro Gly Ser Ala Gln Gln Arg Phe Thr  
 65 70 75 80  
 Gln Val Ser Asp Glu Leu Phe Gln Gly Gly Pro Asn Trp Gly Arg Leu  
 85 90 95  
 Val Ala Phe Phe Val Phe Gly Ala Ala Leu Cys Ala Glu Ser Val Asn  
 100 105 110  
 Lys Glu Met Glu Pro Leu Val Gly Gln Val Gln Asp Trp ~~Trp~~ <sup>Met</sup> Val Ala  
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 Tyr Leu Glu Thr Arg Leu Ala Asp Trp Ile His Ser Ser Gly Gly Trp  
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 Ala ~~Asp~~ <sup>Glu</sup> Phe Thr Ala Leu Tyr Gly Asp Gly Ala Leu Glu ~~Asp~~ <sup>Glu</sup> Ala Arg  
 145 150 155 160  
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 165 170 175  
 Ala Val Ala Leu Gly Ala Leu Val Thr Val Gly Ala Phe Phe Ala Ser  
 180 185 190  
 Lys

atg gcg acc cca gcc tcg gcc cca gac aca cgg gct ctg gtg gca gac	48
Met Ala Thr Pro Ala Ser Ala Pro Asp Thr Arg Ala Leu Val Ala Asp	
1 5 10 15	
ttt gta ggt tat aag ctg agg cag aag ggt tat gtc tgt gga gct ggc	96
Phe Val Gly Tyr Lys Leu Arg Gln Lys Gly Tyr Val Cys Gly Ala Gly	
20 25 30	
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Pro Gly Glu Gly Pro Ala Ala Asp Pro Leu His Gln Ala Met Arg Ala	
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Ala Gly Asp Glu Phe Glu Thr Arg Phe Arg Arg Thr Phe Ser Asp Leu	
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Gln Val Ser Asp Glu Leu Phe Gln Gly Gly Pro Asn Trp Gly Arg Leu	
85 90 95	
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Val Ala Phe Phe Val Phe Gly Ala Ala Leu Cys Ala Glu Ser Val Asn	
100 105 110	
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Lys Glu Met Glu Pro Leu Val Gly Gln Val Gln Glu Trp Met Val Ala	
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Ala Glu Phe Thr Ala Leu Tyr Gly Asp Gly Ala Leu Glu Glu Ala Arg	
145 150 155 160	
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Arg Leu Arg Glu Gly Asn Trp Ala Ser Val Arg Thr Val Leu Thr Gly	
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Ala Val Ala Leu Gly Ala Leu Val Thr Val Gly Ala Phe Phe Ala Ser	
180 185 190	
aag tgaa	583
Lys	

Figure 9A

atg gcg acc cca gcc tca acc cca gac aca cgg gct cta gtg gct gac	48
Met Ala Thr Pro Ala Ser Thr Pro Asp Thr Arg Ala Leu Val Ala Asp	
1 5 10 15	
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Phe Val Gly Tyr Arg Leu Arg Gln Lys Gly Tyr Val Cys Gly Ala Gly	
20 25 30	
cct ggg gaa ggc cca gcc gcc gac ccg ctg cac caa gcc atg cgg gct	144
Pro Gly Glu Gly Pro Ala Ala Asp Pro Leu His Gln Ala Met Arg Ala	
35 40 45	
gct gga gac gag ttt gag acc cgt ttc cgc cgc acc ttc tct gac ctg	192
Ala Gly Asp Glu Phe Glu Thr Arg Phe Arg Arg Thr Phe Ser Asp Leu	
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gcc gct cag cta cac gtg acc cca ggc tca gcc cag caa cgc ttc acc	240
Ala Ala Gln Leu His Val Thr Pro Gly Ser Ala Gln Gln Arg Phe Thr	
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Val Ala Phe Phe Val Phe Gly Ala Ala Leu Cys Ala Glu Ser Val Asn	
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Lys Glu Met Glu Pro Leu Val Gly Gln Val Gln Asp Trp Met Val Ala	
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Tyr Leu Glu Thr Arg Leu Ala Asp Trp Ile His Ser Ser Gly Gly Trp	
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180 185 190	
aag tga	582
Lys	

Figure 9B